UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION LLC, Plaintiff, v. WILLOWOOD, LLC, WILLOWOOD USA, LLC, WILLOWOOD AZOXYSTROBIN, LLC, and WILLOWOOD LIMITED, Defendants.	)	Civil Action No. 1:15-CV-274

STATEMENT OF INTEREST OF THE UNITED STATES

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The undersigned attorneys for the United States ("the government") appear on behalf of the Environmental Protection Agency ("EPA") pursuant to 28 U.S.C. § 517 to inform the Court of the government's position regarding the copyright-infringement allegations asserted by Plaintiff Syngenta Crop Protection, LLC ("Syngenta") in this case against the product labeling of Defendants Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited (collectively, "Willowood").[1] Dkt. No. 1 at 22-25 (Counts V and VI).

I. SUMMARY OF ARGUMENT

Copyright-infringement claims, like Syngenta's, against generic or "me too" or pesticide labels (here, Willowood's labels) should be dismissed for three reasons: (1) proper interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the governing statute, endorses copying by "me too" applicants; (2) "me too" registrants possess an implied license; (3) the merger doctrine precludes copyright protections; and (4) the copying of the label is fair use.

First, the legal question presented here closely resembles the situation and statute addressed by the Second Circuit in *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc.* Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, a generic pharmaceutical manufacturer filing an

[1] The government takes no position on the other claims Syngenta includes in its complaint, *i.e.*, its claims of patent infringement and unfair and deceptive trade practices. Dkt. No. 1 at 1 (¶ 1).

Abbreviated New Drug Application ("ANDA") based on a brand-name drug must propose the "same" labeling as the brand-name drug. When faced with a copyright-infringement claim, the Second Circuit reasoned that copyright law should be construed to accommodate the purpose of the labeling provisions of the Hatch-Waxman Amendments, and thus found no copyright claim could be brought. The court noted that this interpretation preserves the narrow purposes of the ANDA law, which was passed after the 1976 Copyright Act, while not significantly affecting the breadth of copyright protection (nor adversely impacting its purpose to deter free riders).

Similarly, "me too" pesticide labeling should be exempt from copyright-infringement actions, so as to protect Congress' intent to expedite market access for pesticide products that are identical or substantially similar to existing products in composition and labeling. FIFRA establishes expedited review times for such products because they are expected to need only limited review. Moreover, similarity in labeling avoids consumer confusion, reduces the potential for misuse, and conserves EPA resources. Copyright-infringement actions, like Syngenta's, seriously undermine those aims. At the same time, precluding such claims would not seriously impede the broader purposes of the Copyright Act, as the commercial value of pesticide products lies principally with approval of the product, not the labeling.

Second, the owner of the copyrighted label (here, Syngenta) has granted an implied license to "me too" applicants by participating in the FIFRA labeling scheme, which explicitly permits the copying of its labels. Courts can imply a nonexclusive

license to a copyrighted work based on the parties' conduct and intent. Here, an original registrant like Syngenta, under the "me too" provisions, has knowingly and clearly assented to the label copying permitted to "me too" applicants under FIFRA.

Third, under the doctrine of merger, "me too" labeling should be exempt from infringement claims. Under this doctrine, copyright protection is not extended to material that can only be expressed in a limited number of ways. Here, FIFRA labels require risk mitigation and conditions of use that can only be expressed in a limited number of ways--sometimes in only one way and often in fewer ways than would be necessary to accommodate hundreds of "me too" pesticides labels.

Fourth, application of the copyright doctrine of fair use also supports the government's position. Contrary to Syngenta's arguments, section 107 of the Copyright Act does not restrict the doctrine to particular types or categories of use. Instead, courts apply a four-factor test to determine whether alleged copying is legally exempted as a "fair use": 1) the purpose and character of the use including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the entire copyrighted work; and (4) the effect of the use upon the potential market for the copyrighted work.

Weighing these factors favors finding a fair use for "me too" labeling. The pesticide label itself has limited, if any, commercial purpose, and the EPA-required labeling is factual in nature. While a large portion of the "me too" label may be copied or

very similar to an existing label, FIFRA specifically authorizes (and EPA prefers) labeling that is "identical or substantially similar" to the original product. Finally, the use has no real effect on the market for pesticide labels, which by themselves have no commercial value.

II. BACKGROUND

A. Regulation of Pesticides and Pesticide Labeling under FIFRA

1. In General

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136y, assigns EPA the responsibility to administer the national pesticide registration program. Under FIFRA, a pesticide generally may not be sold or distributed unless EPA has registered that product. *Id.* § 136a. EPA issues a registration only after determining that a pesticide's labeling complies with FIFRA and that "when used in accordance with widespread and commonly recognized practice [the pesticide] will not cause unreasonable adverse effects on the environment." *Id*. § 136a(c)(5) (hereinafter, the "FIFRA standard").

To determine whether a pesticide meets the FIFRA standard, EPA requires and reviews (1) a substantial amount of toxicity and exposure data on the pesticide and (2) draft labels. *See* 40 C.F.R. §§ 156, 158. All pesticide applicants are required to either submit their own data or cite to relevant previously submitted data and, where appropriate, provide an offer of compensation for the original data. *Id*. § 152.50(f). The applicant must also submit proposed product labeling. *Id*. § 152.50(e).

When data are submitted, EPA reviews the data and conducts a risk assessment to identify any risks associated with use of the pesticide. EPA then uses that risk assessment and considers the pesticide's benefits to determine whether any terms and conditions of registration are necessary to prevent unreasonable adverse effects on the environment and to evaluate whether labeling language will ensure that the pesticide's use is consistent with the FIFRA standard. *See* 7 U.S.C. § 136a(c)(5); 40 C.F.R. §§ 152.107, 152.112.

The EPA-approved labeling is an integral part of the registration. The labeling (which includes the label attached to the pesticide container and any other material accompanying the pesticide, *see* 7 U.S.C. § 136(p)) is the primary means through which EPA establishes and enforces the terms of the registration and regulates the use of the pesticide. Indeed, it is a violation of FIFRA to use a registered pesticide in a manner inconsistent with the EPA-approved labeling, *id*. § 136j(a)(2)(G). Pesticide labeling sets forth the lawful conditions of use for a pesticide in order to ensure that it will not cause unreasonable adverse effects on the environment. As such, the overarching principle of labeling is that it be clear and understandable to the user.

This principle is carried through the three chief sources EPA considers in assessing whether the label language meets the FIFRA standard: FIFRA, 7 U.S.C. § 136(q); EPA regulations, 40 C.F.R. § 156; and the Agency's Label Review Manual (*available at* https://www.epa.gov/ pesticide-registration/label-review-manual). First, FIFRA directs labeling to contain, among other things, directions for use "which are

necessary for effecting the purpose for which the product is intended and if complied with . . . are adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(F). Failure to meet this requirement renders a pesticide "misbranded," and selling or distributing a misbranded pesticide violates FIFRA. *Id*. §§ 136(q), 136j(a)(1)(E). EPA regulations also prescribe many statements to be used if warranted by the pesticide's hazard profile and require certain content, including an ingredient statement, precautionary statements, and directions for use.[2] *See* 40 C.F.R. § 156.10 (linking to other portions of part 156). EPA's regulations also require the label's directions for use to "be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide." *Id*. § 156.10(i)(1)(i). EPA's Label Review Manual ("Manual") also provides guidance to EPA reviewers and the regulated community for ensuring that the labeling meets the FIFRA standard while also being readable, unambiguous, and enforceable. Manual at 1-2. The Manual also contains several examples of label language that can be used as appropriate.[3] As the Manual explains, "[a] critical function of the label is to translate the results of the science evaluations into a set of conditions, directions and precautions that define who may use a pesticide, as well as where, how, how much, and how often it may be used." *Id*.

[2] As shown in Exhibit 1, a demonstrative, EPA's regulations prescribe exact language for several portions of the label (shown in annotated highlighting) that must or can be used depending on toxicity profile or use pattern of the pesticide.

[3] Exhibit 1 also indicates how the Manual provides language that can be used in labels.

For pesticides that present similar risks, use sites and pests, the label language varies little. This is because appropriate use directions, warning statements, and other aspects of the EPA-approved labeling are directly tied to the EPA's assessment of potential risk concerns.[4] Once the determination is made that certain use restrictions or risk mitigation language are necessary—often a process that involves discussions and negotiations with the applicant, EPA requires that language to that effect appear on the label. Selecting the particular label language to express those concepts is largely a ministerial or mechanistic process, often reflecting language required by regulations, suggested by EPA guidance, or borrowed from other pesticides with similar risk concerns.[5] Because it is critical that the label be as clear and understandable as possible, EPA generally prefers applicants to use language and format with which pesticide users will be familiar, especially for products that present the same types of risk issues, as this reduces the potential for misunderstanding and misuse.

[4] For example, if, after reviewing the applicant's data, EPA determines that a particular pesticide is harmful to fish, EPA may impose a no-use buffer zone around water bodies as a condition for approval. Similarly, if EPA determines that a particular pesticide poses a risk to workers, EPA may require the use of personal protective equipment, like gloves or respirators.

[5] Contrary to the assertion of Syngenta and other original registrants, most resources expended by a pesticide registrant relate to time and expense to develop the data and EPA's time to assess the potential risks and benefits of the pesticide, not to developing label language. *Cf.* Dkt. No. 1 at 8 ¶¶ 26-28; Dkt. No. 109 at 24 (conflating Syngenta's labeling work with "thousands of [safety and efficacy] trials and studies"); s*ee* Ex. 1 (showing that extensive labeling language required or suggested by EPA).

2. "Me Too" Registration

For pesticide products that "would be *identical or substantially similar in composition and labeling* to a currently-registered pesticide … or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment," FIFRA provides an expedited review process. 7 U.S.C. § 136a(c)(3)(B) (emphasis added) (hereinafter, the "'me too' standard")[6]; *see also id*. § 136a(c)(7)(A). These pesticides are generally referred to as "generic" or "me too" pesticides.

The purpose of these provisions is to permit "me too" registrants to share the market with existing registrants under the same conditions. In 1978, Congress, out of concern for "unequal treatment of similar products" and in an effort to encourage market fairness and competition, specifically authorized EPA to approve "me too" products based primarily on their similarity in composition and use to existing pesticide products. *See* Staff of Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., Federal Pesticide Act of 1978 (Comm. Print 1979) at 180-81; Report of the Senate Comm. on Agriculture, Nutrition, and Forestry, S. Rep. 95-334, 95th Cong., 1st Sess. (July 6, 1977) at 4. Congress also intended review of these products to be relatively streamlined by allowing EPA to chiefly review just the product's composition and labeling, on the

[6] Contrary to Syngenta's assertion, Dkt. No. 109 at 25-26, FIFRA clearly authorizes the use of identical or substantially similar labeling.

grounds that "identical or substantially similar" pesticides will present the same level of risks and benefits as the already registered pesticides.[7]

In turn, FIFRA drastically restricts EPA's review periods. Under the Pesticide Registration Improvement Act ("PRIA"), first enacted in 2004,[8] Congress established timeframes for the review of "me too" applications and has generally assigned less time to review a "me too" product than for pesticides containing new active ingredients. For many "me-too" pesticides, EPA is required to grant or deny the registration application no later than four months after receiving it. *See, e.g.*, 7 U.S.C. § 136w-8(b)(3) (Table 4, R300). In contrast, the decision-review periods for pesticide products with new active ingredients are generally much longer—14-24 months—in order to accommodate the additional time and effort required for review. *See id*. § 136w-8(b)(3) (Table 1). For "me too" actions without a PRIA-designated decision-review period, FIFRA requires EPA to issue a decision no later than 90 days after receipt of a complete application. *Id*. § 136a(c)(3)(B)(ii)(II).

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[7] A "me too" applicant needs to provide data and labeling that demonstrate that it meets the "me too" standard, and will often cite to and pay compensation for data previously submitted by another registrant (rather than develop its own data). 7 U.S.C. §§ 136a(c)(1)(D), 136a(c)(1)(F)(iii); *see also Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 571 (1985); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 993-94 (1984). More extensive differences between the registered product and the "me too" product may require additional data and incremental risk assessment.

[8] Because PRIA has a built-in expiration date, it has been reauthorized several times. The most recent version, known as PRIA 3, was adopted in 2012. Pub. L. No. 112-177, 126 Stat. 1327 (Sept. 28, 2012) (amending FIFRA section 33, 7 U.S.C. § 136w-8).

In establishing these new "me too" provisions, Congress did not define the terms "identical," "substantially similar," or "differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." Nor does EPA have a bright line test for distinguishing between labels that are "substantially similar" and those that "differ only in ways."[9] Where "me too" products contain the same active ingredient and are intended to be used in the same manner as an already registered product, there is a presumption that no additional data or review is necessary as the product presents similar risks. Accordingly, the "me too" label needs to convey the same or similar conditions of use as the original registered product.

In practice, EPA generally encourages applicants to use labeling language that is either identical or substantially similar to that on an already registered product. The

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[9] For assessing whether "me too" products can be registered under section 136a(c)(7)(A), however, EPA has explained the level of analysis and additional data required for "substantially similar" or "differ only in ways" "me too" products:

> Although the proposed regulation did not define the term "substantially similar," the Agency stated that it deemed a product "substantially similar" for purposes of incremental risk assessment if it has a composition and uses which fall within the range of composition and uses of currently registered products with the same active ingredient. The Agency would not require any additional data to approve conditional registration of such products.
>
> …[P]roducts which are neither "identical" nor "substantially similar" to currently registered products and which do not contain a "new use" -- are examined more closely in the incremental risk assessment process and applicants may be required to submit additional data.

48 Fed. Reg. 34,000 (July 26, 1983).

Label Review Manual instructs the reviewer to make a "side-by-side" comparison of the proposed set of use directions on the "me too" product to that provided with the original registration. Manual at 11-9.[10] While the format need not be identical, the critical information must remain the same. *Id*. at 11-9, 11-10.

EPA's preference for "identical or substantially similar" labeling reflects the expectation that these products are generally subject to shorter review periods. Greater consistency between labeling also reduces the potential for misinterpretations and misuse and helps preserve EPA resources. Conversely, increased variability in labeling language provides greater opportunity for misuse due to user confusion and requires far greater EPA resources to determine whether such differences may "significantly increase the risk of unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(3)(B). To date, EPA has registered thousands of "me too" products and most of their labels largely use language that is identical or substantially similar to labels used by the original registrants.[11]

[10] EPA encourages the submission of labeling in an electronic form, in a text searchable .pdf format, which helps to improve EPA review efficiency. Manual at 3-10. Submission of electronic labeling enables EPA to use a computer program to compare "me too" and original labels to identify any differences that require evaluation and to ensure conformance to standardized label text requirements. *Id*. at 4-1, 4-2.

[11] Approximately 15-20% of the incoming actions covered by PRIA are "me too" applications.

B. The Present Case

1. Factual Background

Syngenta markets its QUADRIS® Flowable Fungicide and QUILT XCEL® fungicide products under approved EPA labels and have registered their labels with the U.S. Copyright Office. Dkt. No. 1 at 9-10 (¶¶ 29-30, 32, 33, 35); Dkt. Nos. 1-12 to 1-14. In August 2013, Willowood filed "me too" applications with EPA for its Azoxy 2SC and AzoxyProp Xtra products, which correspond, in composition and labeling, to the QUADRIS® Flowable Fungicide and QUILT XCEL® products, respectively. Dkt. No. 1 at 11 (¶ 42); Dkt. No. 1-12; Dkt. Nos. 1-16, 1-17. In June 2014, EPA approved the "me too" registrations for Willowood's products, Dkt. No. 1 at ¶ 1. Roughly nine months later, Syngenta filed the present suit alleging, *inter alia*, that Willowood's labels are "substantially similar" to Syngenta's labels (*id*. at 13 (¶ 52), 23 (¶ 111)) and therefore infringe Syngenta's copyrights. *Id*. at 22-25 (¶¶ 109-28) (Counts V, VI).

Thereafter, Willowood submitted requests for labeling amendments for EPA approval to avoid copyright-infringement claims. The initial amendments to the AzoxyProp Xtra (Ex. 2, submitted in May 2015) and Azoxy 2SC labels (Ex. 3, submitted in October 2015) changed substantial portions of the formatting, and to some extent, the substance of the already approved Willowood "me too" labeling at issue in this case. EPA required several additional revisions to the labeling--two for AzoxyProp Xtra (Exs. 4-5) and one for Azoxy 2SC (Ex. 6)--in order to improve clarity and ensure that the "me too" would continue to meet the FIFRA standard. EPA finally approved revised labeling,

Exs. 7-8, that differs only in fairly minor ways from the previously approved Willowood labeling. *See* Exs. 9-10 (demonstratives showing final, overall changes to the labeling). Syngenta nonetheless asserts that the new Willowood labeling still infringes their copyrighted labeling. Dkt. No. 109 at 13 (¶ 24).

2. Procedural Background

Willowood has moved for summary judgment on Syngenta's copyright-infringement claims, and Syngenta has opposed. Dkt. Nos. 88, 109. This Statement addresses many arguments briefed by both parties, but does not address whether pesticide labeling (or other consumer labeling) generally should be subject to copyright protection, an issue raised by Willowood regarding Syngenta's labeling. Dkt. No. 88 at 24-26.

EPA is concerned about "me too" copyright claims like Syngenta's[12] (which are becoming more prevalent) and their implications for FIFRA-mandated "me too" labeling. Since the *FMC* case in 2005,[13] EPA has been contacted on five other occasions to clarify

[12] Notably, Syngenta highlights virtually all the content of Willowood's labels to show the extent of the alleged copying. Dkt. Nos. 1-26, 1-27. This broad claim, however, implicates a number of statements required or suggested by EPA. EPA prepared Exhibit 1 to highlight several statements on Syngenta's QUADRIS® Flowable Fungicide label that are (i) explicitly required by EPA regulations or as conditions of approval, (ii) recognized as typical in EPA's regulations, or (iii) suggested in the Manual and other guidance documents. The highlighted language is intended to be illustrative and not an exhaustive rendering of all the EPA-mandated language on that label. A deeper dive into the history and risk assessments of this product, as well as a comparison to other labels may reveal other required or standard language, *e.g.*, "avoid spray drift."

[13] *FMC Corp. v. Control Solutions, Inc*. 369 F. Supp. 2d 539 (E.D. Pa. 2005).

its position on this matter and has consistently opposed the application of copyright protection to "me too" labels. *See* Ex. 11; Dkt. Nos. 88-8, 88-9.[14]

III. ARGUMENT

Copyright claims against "me too" labeling, like Syngenta's claims, should be dismissed. The Copyright Act of 1976 protects "original works of authorship fixed in any tangible medium of expression." 17 U.S.C. § 102. To prove infringement, a plaintiff must prove that the "defendant copied the original elements of that copyright." *Lyons P'ship v. Morris Costumes, Inc*., 243 F.3d 789, 801 (4th Cir. 2001). "When the plaintiff possesses no direct evidence that the defendant copied its protected work, it may create a presumption of copying by establishing that the defendant had access to the copyrighted work and that the defendant's work is '*substantially similar*' to the protected material." *Id*. (internal citation omitted) (emphasis added). "To show substantial similarity, the plaintiff must establish that the two works are both 'extrinsically' and 'intrinsically'

[14] Syngenta has moved to exclude the declarations of Lois Rossi (Dkt. No. 88-8) and Debra Edwards (Dkt. No. 88-9), two former EPA officials who prepared declarations in earlier cases. *See* Dkt. No. 107 at 6-7, 14-17. As Syngenta admits, these declarations "advance policy arguments for why pesticide labels should not be copyrightable" under the "identical or substantially similar" FIFRA standard for "me too" labels. *Id*. at 6. Syngenta argues that both should be excluded because the declarations-at-issue were "submitted eight to ten years ago in two unrelated cases" and neither case was resolved on the merits. *Id*. at 7. The government, however, believes that these declarations accurately reflected, and for the most part, still accurately reflect EPA practices with regard to "me too" applications.

similar." *Humphreys & Partners Architects, L.P. v. Lessard Design, Inc.*, 790 F.3d 532, 537-38 (4th Cir. 2015) (citations omitted).[15]

As discussed below, any "me too" labeling, including Willowood's, is likely to infringe under this "substantial similarity" test, as "me too" registrants must comply with the statutory standard of being "identical or substantially similar" to the original registrant's labeling. But, if viewed under the basic principles of statutory construction, or alternatively, in accordance with the copyright doctrines of implied license, merger and fair use, such copyright claims should be dismissed.

A. A Proper Interpretation of FIFRA's Labeling Provisions Should Preclude Copyright-Infringement Claims.

A proper interpretation of FIFRA's "me too" provisions and their statutory purposes precludes copyright claims against "me too" labeling, such as Syngenta's claim against Willowood. Congress specifically amended FIFRA to facilitate the registration of "me too" products in order to allow greater marketplace competition. *See supra* Part II.A.2. For products that are "identical or substantially similar in composition and labeling to a currently-registered pesticide," FIFRA provides for expedited processing. To meet these deadlines, efficiently use resources, ensure label clarity, and avoid

[15] In the Fourth Circuit, "the court must [first] determine whether the two works are 'extrinsically similar because they contain substantially similar ideas that are subject to copyright protection.' And second, the court must ask whether the works are 'intrinsically similar' in the sense that they express those ideas in a substantially similar manner from the perspective of the intended audience . . . ." *Lyons*, 243 F.3d at 801 (quoting *Towler v. Sayles*, 76 F.3d 579, 583-84 (4th Cir. 1996)).

potential confusion and misuse by the user (and thus potential unreasonable adverse effects to the environment), EPA encourages the use of "me too" label language that is identical or substantially similar to already registered pesticide label language. *See id.*

If copyright actions like Syngenta's are successful and become even more prevalent, EPA's ability to timely issue "me too" pesticide registrations would be negatively affected. Determining whether a "me too" label—which is not identical or substantially similar to the registered product that it mirrors—would meet the FIFRA standard is a much more complicated task, requiring substantially more resources than reviewing identical or substantially similar labeling. EPA's experience and authority under FIFRA is in evaluating whether pesticides meet the FIFRA standard and whether "me too" pesticide and their labels are sufficiently similar to those products that are already registered, not whether label language avoids potential copyright-infringement claims. On a broader programmatic level, if the resources required for each of those registrations were exponentially increased due to longer label-review times compelled by copyright concerns, this would frustrate Congress' objectives to expedite review and streamline registration of "me too" pesticide products.

1. The Second Circuit Similarly Barred Copyright Actions Against Generic Drug Labels.

The Second Circuit addressed a similar issue and a similar statutory directive in *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21,

27 (2d Cir. 2000), which involved label copying[16] in an approved Abbreviated New Drug Application ("ANDA") for a generic version of SmithKline's Nicorette®, a nicotine gum. Under the Hatch-Waxman Amendments[17] to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the aspiring generic manufacturer was required to propose product labeling that was "the *same* as the labeling approved for" Nicorette®. *SmithKline*, 211 F.3d at 23 (quoting 21 U.S.C. § 355(j)(2)(A)(v)) (emphasis added). Accordingly, the Food and Drug Administration ("FDA") will refuse an ANDA if the application is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug . . . ." 21 C.F.R. § 314.127(a)(7).

SmithKline sued Watson[18] for infringement of SmithKline's copyrighted product labeling. *SmithKline*, 211 F.3d at 23-24. While Watson attempted to amend its labeling to avoid infringement, FDA ultimately "'adhered to its decision to require Watson copy verbatim most of the SmithKline' user guide," which contained the labeling at issue. *Id.*

[16] The government submitted an *amicus* brief in that case. *See* Brief for the United States as *Amicus Curie*, *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000), 2000 WL 34003890.

[17] The Amendments were implemented as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271).

[18] Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively, Watson) together obtained approval to sell a generic version of Nicorette®. *SmithKline*, 211 F.3d at 23.

at 24 (quoting *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, No. 99 Civ. 9214, 1999 WL 1243894, at *4 (S.D.N.Y. Dec. 22, 1999)).

Given the clear statutory directive that the labeling be the "same," the Second Circuit found that the generic manufacturer "cannot be liable for copyright infringement because the Hatch-Waxman Amendments require generic drug producers to use the same labeling as the producer of the pioneer drug." *SmithKline*, 211 F.3d at 23. Though acknowledging that "same" does not mean "identical" under the statute, the court concluded that "a legislative drafter would believe that a sameness requirement would lead to the creation of works that would easily fall within the copyright law's infringement test of 'substantial similarity.'" *Id.* at 27 (citing *Hamil Am., Inc. v. G.F.I.*, 193 F.2d 92, 99 (2d Cir. 1999)). In light of this conflict, the court determined that it should adopt an interpretation that "preserves the principal purposes of" each statute. *SmithKline*, 211 F.3d at 27-28 (citing *Zenith Elecs. Corp. v. Exzex, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999)).

The Second Circuit reasoned that the underlying purpose of the Hatch-Waxman Act Amendments (passed after the Copyright Act) was to facilitate introduction of generic competitors by allowing them to "piggy-back upon the pioneer producer's successful FDA application." *SmithKline*, 211 F.3d at 28. In view of that statutory scheme, the Second Circuit found that the copying of the labeling for an ANDA did not constitute copyright infringement because the statute and the FDA required that the labeling be the same in order to streamline approval for the generic drug. *Id.* at 23.

Specifically, it noted that "both time of enactment and specificity favor[ed] [its] interpretation: the Hatch-Waxman Amendments were enacted subsequent to the Copyright Act of 1976, and the Copyright Act's broad generality contrasts with the Hatch-Waxman Amendments specific drug approval scheme." *Id*. at 28 n.3.

In so doing, the court explained that it was not undermining the purpose of copyright law. The "profit sought by the creator of the pioneer drug label flows primarily from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow." *Id*. at 29. Thus, the underlying purpose of copyrights, to protect authors from free riders and thereby economically encourage artistic creativity, "is not seriously implicated." *Id*. (citation omitted).

The same rationale applies here, with the same result. FIFRA requires that the labeling be "identical or substantially similar" or "differ … only in ways that would not significantly increase the risk of unreasonable adverse [environmental] effects" in order to expedite and streamline the registration process. *See* 7 U.S.C. § 136a(c)(3)(B)(i). Similar to the "same" standard for generic drug labeling, compliance with FIFRA's "me too" standard necessitates that "me too" labels will be either identical or fall within the "substantial similarity" test.[19] In this case, Syngenta's continued allegations of

[19] As indicated above, EPA does not delineate between what label language qualifies as "substantially similar" and what "differs only in ways…" It is sufficient for EPA purposes that the language on the label ensures that the pesticide poses similar risks to the environment as the original product. The combination of product similarity and expectation of similar instructions for such products, the limited ways of expressing the

infringement, even after Willowood successfully revised its labels, strongly support this point. Dkt. No. 109 at 13 (¶ 24).

Similarity in labeling facilitates expedited review and approval of the generic, or "me too," pesticide in accordance with the statutory scheme. As with *SmithKline*, the copyright laws would not be undermined by a similar finding for FIFRA "me too" labeling. Like the Hatch-Waxman Amendments, the FIFRA "me too" provisions, passed two years after the 1976 Copyright Act, specifically authorize "identical or substantially similar" labeling. Moreover, the "me too" provisions do not undercut the profits of original pesticide registrants, as most of its profitability comes from its registration, and EPA's determination that the product meets the FIFRA standard, not from simply the label itself. Most of an applicant's costs associated with getting EPA approval for pesticides relates to developing data to support the registration, not to drafting labels, and Congress has set up provisions to ensure adequate compensation for that data. *See infra* note 20. When Congress established the "me too" provisions, it also recognized the original registrant's innovation and intellectual property concerns, in developing data to support the registration, data upon which the labeling is based. *See* Staff of Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., Federal Pesticide Act of 1978 (Comm. Print 1979) at 63-66, 137-139.[20]

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necessary concepts, and the limited review periods underscore the value of identical or very similar language. *See supra* Part II.A.2.

[20] Congress provided a scheme to ensure adequate compensation and recognition of that effort: a period of "exclusive use," *i.e.*, a 10-year-plus period during which

Conversely, the FIFRA "me too" process is likely to be adversely affected by enforcement of label copyrights. It would impede efforts to review labeling under the "me too" standard and effectively strike language from FIFRA clearly intended to facilitate registration of pesticide products that are the same as what is already on the market. In practical terms, it would drastically limit the number of "me too" products that could be approved, since it would be difficult, especially for commonly used pesticides, for every individual label to avoid the "substantial similarity" test of copyright infringement.

2. The *FMC* Court Incorrectly Distinguished *SmithKline*.

Relying on the *FMC* district-court decision, Syngenta argues that *SmithKline* is distinguishable "because FIFRA does not require identical language on 'me too' products." Dkt. No. 109 at 27 (citing *FMC*, 369 F. Supp. 2d at 569-70). In *FMC*, the court found that "the plain wording of the EPA labeling statutes and regulations do not mandate copying, but rather suggest generic companies draft their own language." *FMC*, 369 F. Supp. 2d at 568 (citations omitted). The *FMC* decision was based, in part, on the fact that "there was no evidence from or on behalf of the EPA to advance the notion that

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applicants cannot rely on data without the original data submitter's permission, and a 15-year period during which anyone citing to the original data must provide compensation to rely on the data. *See* Staff of Senate Comm. on Agriculture, Nutrition, and Forestry, 95th Cong., Federal Pesticide Act of 1978 (Comm. Print 1979) at 63-66, 137-139; 7 U.S.C. § 136a(c)(1)(F). Congress did not recognize a separate need to provide compensation for the label itself.

the EPA requires generic or me-too applicants to copy the label language from the pioneer pesticide product." *Id*. at 568-69.

The government believes the *FMC* court misapprehended the EPA labeling scheme, ignored significant impacts that its findings would have on EPA's pesticide labeling program, and thus failed to recognize the parallel situation that existed in *SmithKline*.[21] Specifically, the court failed to acknowledge that the "me too" standard essentially requires the generic applicant to provide labeling that falls within the "substantial similarity" test of copyright infringement. The *FMC* court found that FMC, the copyright holder, "made a persuasive evidentiary showing that verbatim or nearly wholesale copying of another registrant's label is unnecessary to obtain expedited review by the EPA of a label." *FMC*, 369 F. Supp. 2d at 560. As discussed above, the government disputes this understanding of its review process because the FIFRA "me too" standard, which is intended to streamline review and registration of "me too" products, endorses label copying. This statutory mandate should not be expunged from FIFRA due to conflicts with copyright law. By erring in this way, *FMC* improperly found that FMC's copyright claim presented no conflict between FIFRA and the Copyright Act. *Id*. at 570.

Acknowledging *FMC*'s statements regarding the lack of EPA intervention, Syngenta further argues that even if EPA intervened in this matter, "it would be

[21] As the parties acknowledge (Dkt. No. 88 at 20 n. 14; Dkt. No. 109 at 27 n. 6), the government did not participate in *FMC*.

irrelevant, because the ability to set aside copyright protection in light of alleged policy rationales underlying FIFRA lies not with the Court, but with Congress." Dkt. No. 109 at 27 n.6. This is untrue. As the Second Circuit acknowledged in *SmithKline*, "where two laws are in conflict, courts should adopt the interpretation that preserves the principal purposes of each." *SmithKline*, 211 F.3d at 28-29 (citing *Zenith Elecs. Corp. v. Extec, Inc.*, 182 F.3d 1340 (Fed. Cir. 1999)). Accordingly, this Court should adopt the government's position because it preserves the specific mandates of FIFRA for "me too" labels without undermining the purposes of the Copyright Act.

B. "Me Too" Applicants Are Granted an Implied License.

"Me too" applicants should also have an implied license to the copyrighted labeling. By submitting its application for registration under the FIFRA scheme, original registrants, like Syngenta, impliedly agree that "me too" applicants can use its labeling for "me too" registration without fear of being sued for infringement.

The Fourth Circuit has recognized that an implied nonexclusive license constitutes an affirmative defense to a claim of copyright infringement. *Nelson-Salabes v. Morningside*, 284 F.3d 505, 514 (4th Cir. 2002). Where there is no written license, a license can be implied, either from oral communications or from the parties' conduct. *I.A.E., Inc. v. Shaver*, 74 F.3d 768, 775 (7th Cir. 1996). The Fourth Circuit has used the *Effects Associates* test to determine whether an implied license has been created. *Nelson-Salabes*, 284 F.3d at 514-15. Under that test, a license may be found when (1) a person or entity requests the creation of a work, (2) the creator makes that particular work and

delivers it to the requesting licensee, and (3) the licensor intends that the licensee copy and distribute the work. *Id*. (citing *Effects Assocs., Inc. v. Cohen*, 908 F.2d 555, 558-59 (9th Cir. 1990)). Generally speaking, "[t]he touchstone for finding an implied license, according to this framework, is intent." *John G. Danielson, Inc. v. Winchester-Conant Props., Inc*., 322 F.3d 26, 33 (1st Cir. 2003) (citing *Nelson-Salabes*, 284 F.3d at 515 (calling intent "determinative question")).

All three prongs of the *Effects Associates* test are met here. The first prong requires that an entity request creation of the copyrighted work. Here, the copyrighted labeling was required to be produced and submitted to EPA as part of the FIFRA registration process. *See* Dkt. No. 1 at 8 (¶¶ 26, 29) (describing Syngenta's labeling submissions for regulatory approval).

The second prong requires that the creator make the copyrighted work and deliver it to "the requesting licensee." *Effects Assocs., Inc.*, 908 F.2d at 558-59. A pesticide applicant knowingly and willingly submits its labeling under a regulatory scheme that it knows will permit "me too" applicants to use "identical or substantially similar" language. In this case, Syngenta willingly submitted its labeling to EPA, knowing that future "me too" registrants would likely copy large portions of it. Thus, Syngenta intentionally submitted the labeling with knowledge that EPA may approve future "me too" pesticide registrations using the same labeling, which would then be distributed and sold publicly.

While an original registrant may have no direct dealings with a "me too" applicant, such facts are inconsequential to whether an implied license has been granted or whether the registrant possessed the requisite "intent." Courts, in fact, have held that there is no requirement of privity for an implied license. *See, e.g.*, *Effects Assocs., Inc.*, 908 F.2d at 555-59; *Nat'l Ass'n For Stock Car Racing, Inc. v. Scharle*, 365 F. Supp. 2d 515, 527-28 (E.D. Pa. 2005). In *Effects Associates*, the Ninth Circuit found that the plaintiff had granted an implied license for its copyrighted special effects in a horror film, to both: (1) the film's producers, who negotiated directly with the plaintiff, as well as, (2) the film's distributors, who had no direct dealings with the plaintiff. 908 F.2d at 558-59. Similarly, a registrant delivers its labeling to EPA under a statutory scheme that implicitly permits "me too" registrants to use it to develop their own "identical or substantially similar" labeling. Thus, a registrant like Syngenta knew that its labeling would form the basis of any subsequent "me too" labeling.

Under the third prong of the test, the licensor must intend for the licensee to copy and distribute the copyrighted work. The Fourth Circuit interpreted this "copy and distribute" prong to mean that "the creator of a protected work must intend that its copyrighted drawings be used on the project for which they were created, independent of the creator's involvement." *Nelson-Salabes*, 284 F.3d at 514-15 (citations omitted). Again, FIFRA clearly authorizes labels copied by "me too" registrants. Thus, a registrant like Syngenta clearly intended, or at least assented to, the alleged copying permitted for "me too" registrants.

For all of these reasons, it is reasonable to conclude that registrants like Syngenta have granted an implied nonexclusive license to "me too" registrants, such as Willowood.

C. Copyright Claims Against "Me Too" Labels Should Also Be Dismissed under the Merger Doctrine.

Copyright protection does not "extend to any idea . . . concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work." 17 U.S.C. § 102(b). Under the doctrine of merger, "copyright protection will be denied to even some expressions of ideas if the idea behind the expression is such that it can be expressed only in a very limited number of ways." *Toro Co. v. R & R Products Co.*, 787 F.2d 1208, 1212 (8th Cir. 1986); *see also Yankee Candle Co. v. Bridgewater Candle Co.*, 259 F.3d 25, 36 (1st Cir. 2001); *Ets-Hokin v. Skyy Spirits, Inc*., 225 F.3d 1068, 1082 (9th Cir. 2000). Where an idea and its expression merge, copyright protection will not exist. *See Computer Assocs. Int'l, Inc. v. Altai, Inc.*, 982 F.2d 693, 707-08 (2d Cir. 1992).

Merger typically arises when there is, if not only one form of expression, at best only a limited number, and to permit copyrighting would mean that a party or parties, by copyrighting a mere handful of forms, *could exhaust all possibilities of future use* of the substance." *Morrissey v. Proctor & Gamble Co.*, 379 F.2d 675, 678 (1st Cir. 1967) (emphasis added) (internal citations omitted). For example, the First Circuit found merger where there were a "sharply limited" number of ways to depict fruits and flowers

on labels indicating the scent of candles. *Yankee*, 259 F.3d at 36.[22] Conversely, the doctrine does not apply if an idea can be expressed in "a plurality of totally different manners." *Apple Computer, Inc. v. Franklin Computer Corp*., 714 F.2d 1240, 1253 (3d Cir. 1983) (quoting *Dymow v. Bolton*, 11 F.2d 690, 691 (2d Cir. 1926)).

The same principles should be applied to "me too" labeling. Under the intended statutory and regulatory scheme, a "me too" applicant has a "limited number of ways" of expressing directions for use and associated warnings on the label for its pesticide, which must be similar to an existing registrant label. Even assuming one or two or three "me too" applicants might be able to express the unprescribed use directions and product warnings in a way that meets the "me too" standard but avoids copyright-infringement claims, there are not hundreds of different ways to convey the necessary label information so that all "me too" registrants could avoid copyright. For some pesticides, there are hundreds of "me too" registrants. As explained in the 2006 Rossi Declaration,

[22]Syngenta forwards an unduly restrictive view of the merger doctrine, asserting that it "applies only to situations '[w]here there is essentially only *one way* to express an idea.'" Dkt. No. 109 at 25 (quoting *Soc'y of Holy Transfiguration Monastery, Inc. v. Gregory*, 689 F.3d 29, 53 (1st Cir. 2012)) (emphasis added). As *Gregory* explained, however, "[Even] [w]hen the idea and its expression are not completely inseparable, there may still be only a limited number of ways of expressing the idea," and thus the doctrine still applies. *Holy Transfiguration*, 689 F.3d at 54 (quoting *Yankee Candle*, 259 F.3d at 36).

there were approximately 650 approved 2,4-D products[23] on the market at that time, the majority of which are "me too" products. Dkt. No. 88-8 at 8 (¶ 13).

Moreover, many aspects of a label are prescribed by EPA's regulations.[24] In addition to including use sites, target pests, and application rates, the label must include language required to mitigate potential risks, such as protective equipment or no-spray buffers. These conditions are directly driven by the risk assessment findings, which are essentially the same between an original product and a "me too," making the mitigation language mandatory.

Accordingly, in order to avoid confusion among consumers and reduce the potential for misuse, facilitate enforcement, and efficiently process the numerous "me too" applications, EPA encourages the use of the same or very similar language on "me too" labels. Thus, Ms. Rossi's statement continues to be true: "[m]ost of the many thousands of me-too product labels on the market are in large respect either identical or substantially similar to the labels used by the original registrants of the pesticide."[25] Dkt. No. 88-8 at 7 (¶ 11).

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[23] 2,4-D is a common name for 2,4-Dichlorophenoxyacetic acid, a widely used herbicide.

[24] *See* Exhibit 1 (highlighting and annotating prescribed language on Syngenta label).

[25] *FMC* found that merger did not exist because the defendant's desire to demonstrate to customers that its product was identical to Syngenta was a commercial and competitive objective, which had no effect on merger. 369 F. Supp. 2d at 567. But

This point is reflected in the very labels at issue in this case. As Willowood points out, Dkt. No. 88 at 21-23, Syngenta's labeling sets forth basic instructions to use its products safely and effectively that are required by EPA's regulations or can be expressed in a limited number of ways. For example, Syngenta's Quadris® product labeling[26] (on which Willowood's Azoxy 2SC label is based) includes basic phrases such as "keep out of reach of children," "avoid contact with skin, eyes, or clothing," and "harmful if absorbed through skin."[27] Dkt. No. 1-12 at 1-3. Moreover, though 55 pages long, roughly 30 pages of the label contain charts that instruct a user on how to use the product on particular crops.[28] *Id.* at 19-50; *see also* Dkt. No. 88 at 22 n.15.

Such labeling language is akin to works typically excluded from copyright protection under the merger doctrine. In *ATC Distribution Group, Inc. v. Whatever It Takes Transmissions & Parts, Inc.*, for example, the Sixth Circuit dismissed copyright claims based on a transmission parts catalog that categorized parts by brand, transmission type, and type of part, which had been copied wholesale. 402 F.3d 700, 707-10 (6th Cir.

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the court concludes, without any real analysis, that "other methods of expressing the idea" exist, something the government views as misguided and frequently inaccurate. *Id.*

[26] Syngenta's Quilt Xcel® labeling includes very similar language, posing the same problems for the corresponding Willowood product, AzoxyProp Xtra. Dkt. Nos. 1-14, 1-4.

[27] As shown in Exhibit 1, these statements are required by EPA's regulations or suggested in EPA's Label Review Manual.

[28] As indicated in Exhibit 1, Syngenta's table format is similar to what is found in the Manual and the majority of the content in that table is required by EPA's regulations, 40 CFR § 156.10(i)(2), and based on the risk assessment findings.

2005). The court reasoned that the merger doctrine applied because even if "some strings of numbers used to designate an item or procedure could be sufficiently creative to merit copyright protection, the parts numbers at issue in the case before us do not evidence any such creativity," where the "allocation of numbers to parts was an essentially random process. . . ." *Id.* at 709.

Syngenta nonetheless argues that, while "EPA regulates the safety considerations on pesticide labels, it does not similarly regulate efficacy claims on pesticide labels." Dkt. No. 109 at 24-25 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005)).[29] This is incorrect, as EPA reviews all aspects of the label to ensure that it (1) meets the FIFRA standard and (2) does not include false or misleading information, including efficacy claims. 40 C.F.R. §§ 152.108, 152.112, 152.113, 156.10.

D. Copyright Claims Should Be Dismissed Against "Me Too" Labeling as a "Fair Use" of the Labeling Language.

"Me too" labels should also be deemed to be a fair use of labels copyrighted by an earlier registrant. Under the fair use doctrine, codified in 17 U.S.C. § 107, there are limitations to an author's exclusive rights to a copyrighted work. *See Harper & Row*

[29] The *Bates* Court did not state that EPA does not review the efficacy *language* in labels; rather, it was merely stating that EPA's label approval generally does not reflect an independent determination that the pesticide "will be efficacious or will not damage crops or cause other property damage." *Id*. (quoting Pesticide Registration Notice 96-4, p. 5 (June 3, 1996), *available at* http://epa.gov/oppmsd1/PR Notices/pr96-4.html, App. 235).

Publishers v. Nation Enters., 471 U.S. 539, 549 (1985). Specifically, "the fair use of a copyrighted work, including such use by reproduction . . . for purposes such as criticism, comment, news reporting, teaching, . . . scholarship, or research, is not an infringement of copyright." 17 U.S.C. § 107. The statute continues the common-law tradition of fair use, which recognized that in order to "'promote the Progress of Science and useful Arts'" certain amounts and types of copying must occur. *See Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 575 (1994) (quoting U.S. Const. Amend. I).

Determining a "fair use" is "not to be simplified with bright-line rules, for the statute, like the doctrine it recognizes, calls for case-by-case analysis." *Campbell*, 510 U.S. at 577. The preamble of section 107 specifically recites six uses (activities) likely to result in a finding of fair use: "criticism, comment, news reporting, teaching . . ., scholarship, or research." While Syngenta argues that Willowood's alleged copying in this case does not fall within any of these categories, Dkt. No. 109 at 28, the list is not exhaustive, as the statute's legislative history makes clear.[30] *See Harper & Row*, 471 U.S. at 562; *Pac. & S. Co., Inc. v. Duncan*, 744 F.2d 1490, 1496 (11th Cir. 1984);

[30] The House and Senate Reports for section 107 expand on the list of six purposes, and other examples are found in precedent. H.R. Rep. No. 94–1476, 94th Cong., 2d Sess. 66 (1976); *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 478 (1984); *Triangle Publ'ns, Inc. v. Knight-Ridder Newspapers, Inc.*, 626 F.2d 1171 (5th Cir. 1980) (comparative advertising); 1975 S. Rep. 61-62; 1976 H. Rep. 65; *Iowa State Univ. Research Found., Inc. v. Am. Broad. Co.*, 621 F.2d 57, 60 (2d Cir. 1980).

Cambridge Univ. Press v. Becker, 863 F. Supp. 2d 1190, 1225 (N.D. Ga. 2012). The House Report for section 107 also indicates Congress' intent for a case-by-case review:

> [T]here is no disposition to freeze the doctrine in the statute, especially during a period of rapid technological change. Beyond a very broad statutory explanation of what fair use is and some of the criteria applicable to it, the courts must be free to adapt the doctrine to particular situations on a case-by-case basis.

H.R. Rep. No. 94–1476, 94th Cong., 2d Sess. 66 (1976). Indeed, the Supreme Court has identified additional uses not listed in the preamble of section 107 that can constitute fair use. *See, e.g.*, *Sony Corp. v. Universal City Studios, Inc.*, 464 U.S. 417, 456 (1984) (identifying fair uses with, for example, a voter who copies a news program).

To determine "fair use," a court typically applies a four-factor test. The factors are (1) the purpose and character of the use including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work. *See* 17 U.S.C. § 107; *Harper & Row*, 471 U.S. at 539. Weighing the fair use factors, copying by "me too" applicants, like that alleged against Willowood, should be deemed a fair use.

1. The Primary Purpose of Pesticide Labeling, by Itself, Is Non-Commercial.

The first "purpose and character" factor relates to whether the copyrighted work was copied in good faith to benefit the public or primarily for the commercial interests of the infringer. *Harper & Row*, 471 U.S. at 539. If the alleged infringer is using the

copyrighted work in a manner that benefits society, the use is more likely to be deemed a fair use. *See MCA, Inc. v. Wilson*, 677 F.2d 180, 182 (2d Cir. 1981). The public benefit resulting from a particular use must be considered, notwithstanding the fact that the alleged infringer may also gain commercially. *Sundeman v. Seajay Soc'y, Inc.*, 142 F.3d 194, 203 (4th Cir. 1998). In other words, courts should look at the ultimate purpose of the copying and whether it was benefiting the public or consumers. *See Sega Enterprises Ltd. v. Accolade Inc.*, 977 F.2d 1510, 1523 (9th Cir. 1992) (finding that Accolade copied Sega's software in order to improve compatibility with Sega's console, with only minimal commercial significance to the copying).[31]

While a label is required before a pesticide can be sold, the primary function of a "me too" label is to provide information for public benefit, not for private commercial gain. *See* Dkt. No. 88-8 at 3 (¶ 3). The label's inclusion of precautionary statements and information regarding application sites, target pests, dosage rates, and the method, frequency, and timing of applications, 40 C.F.R. § 156.10, is providing critical information to help pesticide users avoid harm to themselves and the environment. Using identical or substantially similar language is likely to benefit users and the public, by reducing the potential for misuse and unreasonable adverse effects on the environment.

[31] Syngenta argues that *Sega* only stands for the proposition that any commercial exploitation was indirect because it involved copying as an "intermediate step" in product development, whereas the present case somehow involves direct copying of a commercial product. Dkt. No. 109 at 29 (quoting *Sega*, 977 F.2d at 1518, 1522-23). This position ignores that the commercial product is the pesticide, not its statutorily required label.

Furthermore, consistency between labels for identical or substantially similar products improves the EPA's ability to enforce pesticide labeling in a consistent manner.

Although the labeled product has commercial value, the label itself has little or none. While the *FMC* court concluded that a "me too" label is indisputably commercial, 369 F. Supp. 2d at 579, such a conclusion is overly simplistic, in failing to look at the statutorily required label separately from the pesticide product itself.

2. "Me Too" Labeling is Factual in Nature.

The second fair use factor relates to the nature of the copyrighted work. *Harper & Row*, 471 U.S. at 539. When the original work is factual or functional in nature, the copy is much more likely to be considered a fair use. *Sega*, 977 F.2d at 1523-24; *see also* Dkt. No. 88 at 27-28. Copyright law recognizes a greater need to disseminate factual works rather than works of fiction. *Harper & Row*, 471 U.S. at 563; *see also Gulfstream Aerospace Corp. v. Camp Sys. Int'l, Inc.*, 428 F. Supp. 2d 1369, 1378 (S.D. Ga. 2006) (finding that aircraft maintenance manuals were predominantly factual in nature rather than creative).

The copyrighted labeling at issue here is mainly factual. *See id.* at 1378. The directions for use, warnings, and ingredient information conveyed in EPA-required pesticide labels are almost entirely factual. The types of crops and targeted pests, application methods and rates are all dictated by the specific pesticide and its intended use pattern, which is primarily the same between original and "me too" pesticides. Other warnings, mitigation terms, or specific use instructions are determined based on the

potential risks posed by the pesticide as identified in EPA's risk assessments. Thus, the second factor also favors a finding of fair use.

Nonetheless, Syngenta argues that the second factor is of little importance, Dkt. No. 109 at 29, relying on *FMC*'s statement that this factor typically "recedes into insignificance." *FMC*, 369 F. Supp. 2d at 579 (quoting *Nimmer on Copyright* § 13.05[A][2][a]). While it is true that the second factor is not, by itself, determinative, the fair use defense is unquestionably far broader for factual and functional works, such as the labeling-at-issue. *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 531 (9th Cir. 2007) (citing *Nimmer* § 13.05[A][2][a]).

3. A Substantial Amount of Copying Is Necessary for "Me Too" Labels.

The third factor focuses on the amount and substantiality of the work copied. *Harper & Row*, 471 U.S. at 539. There are no absolute rules as to how much of a copyrighted work may be copied and still be considered a fair use. *Sundeman*, 142 F.3d at 202. A court, however, should consider whether the amount of copying is reasonable in view of the purpose of the copying. *Campbell v. Acuff*, 510 U.S. 569, 586 (1994). Where there is an important societal interest, wholesale copying can still qualify as a fair use. *Bond v. Blum*, 317 F.3d 385, 396 (4th Cir. 2003); Dkt. No. 88 at 28 (discussing *Blum*). Thus, while Syngenta correctly acknowledges that "the more of a copyrighted work that is taken, the less likely the use is to be fair,"[32] its analysis fails to take into

[32] Dkt. No. 109 at 30 (citing *Infinity Brad. Corp. v. Kirkwood*, 150 F.3d 104 (2d Cir. 1998)).

account the FIFRA scheme and its regulatory aims, which legally authorize "identical or substantially similar" labeling.[33]

In this case, the pesticide label was copied consistent with the "me too" standard. As stated earlier, Congress established this streamlined "me too" registration process to promote the important societal interest of encouraging market fairness and competition. This aim is greatly facilitated by identical or substantially similar labeling. Such labeling can be reviewed more quickly and will be familiar to users and the enforcement community. Therefore, although there is admittedly a substantial amount of copying by "me too" applicants, like Willowood, it does not tip the third factor in favor of Syngenta.

4. Alleged Copying by "Me Too" Registrants Has No Effect on the Potential Market of the Original Registrant's Labeling.

The fourth factor evaluates the effect on the potential market or value of the copyrighted work. *Harper & Row*, 471 U.S. at 539. The Supreme Court has made clear that this factor is "undoubtedly the single most important element of fair use," *id.* at 566, as it focuses on the underlying purpose behind copyright law—to encourage creative endeavors. *Sony*, 464 U.S. at 450.

A use that does not materially impair the marketability of the copyrighted work generally will be deemed fair. *Sundeman*, 142 F.3d at 206. Here, the pesticide labels do

[33] For similar reasons, the government disagrees with Syngenta's suggestion that there is "no basis to suggest that verbatim copying of a registered label is *necessary* to ensure that a me-too label is consistent and has the same import." Dkt. No. 109 at 29 (emphasis in original). As discussed, the statutory framework for "me too" products requires "identical or substantially similar" labels, in part, for that very reason.

not have a commercial value apart from the products they accompany. *See also* Dkt. No. 88 at 29. An original pesticide label is not marketable except as a required element of a pesticide registration. Therefore, a "me too" label copying an original label cannot affect the marketability of an original label that has no value aside from the pesticide product. Although there is likely to be an economic impact on the sales of the original registrant with the approval of "me too" products, this is the statutorily required scheme. Allowing copyright claims to preclude "identical or substantially similar" labeling would frustrate that objective. Therefore, this factor also weighs in favor of finding fair use.

All four fair-use factors have to be weighed together in light of the purposes of copyright and the fair-use defense. *Campbell*, 510 U.S. at 578. In this case, the FIFRA-mandated "me too" labeling scheme (1) has a non-commercial purpose, (2) is factual in nature, (3) requires substantial copying, and (4) and does not affect the marketability of the existing registrant's copyrighted label. Weighing all four factors, a "me too" registrant's use of identical or substantially similar language to the existing registrant's label strongly supports a finding of fair use.

IV. CONCLUSION

For the reasons stated above, the government believes that copyright claims, like Syngenta's, against "me too" applicants should be dismissed.

February 27, 2017

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document has been filed electronically with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record in this action.

February 27, 2017 /s/Walter W. Brown
Walter W. Brown